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Considerations regarding the emergence and development of patient rights and their application in the pharmaceutical field

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Abstract. This paper aims to highlight the historical evolution of the emergence of patient rights, social rights in their essence, as well as their development according to the essential transformations of a society.
The present paper aims to show the fact that the patient's rights were born, first of all, through quantitative assimilations, through increases and overlapping of information from one era to another, they are not the "creation" of contemporary times, the fact that they are based on a certain history written before our eyes.
The study of the patient's rights is intertwined with the study of political concepts, all the more so since the drafting of legislation is directly dependent on political guidelines, and political institutions are directly involved in the legislative act.
The development of social relations, their complexity, the unprecedented multiplication of intra- and inter-social contacts, determined a correlative development of law and the emergence of community law, which in the current social reality, represents the positive law applicable on the territory of the European Union.

Keywords: patient rights, human rights, EU legislation, political concepts, pharmaceutical field

1. Introduction

The patient's rights were born, first of all, through quantitative assimilations, through increases and overlaps of information from one era to another, they are not the "creation" of contemporary times as they are based on a certain history written before our eyes.

In the study of patients' rights, we must also look at the historical perspective, i.e. the evolution of the concepts and notions with which the law operates, which is an integral part of the social and moral evolution of mankind, reflecting almost directly the political and mental transformations that have taken place in history.

The study of patients' rights is intertwined with the study of political concepts, all the more so as the drafting of legislation is directly dependent on political trends and political institutions are directly involved in the legislative process.

The development of social relations, their complexity, the unprecedented multiplication of intra- and inter-social contacts, have led to a correlative development of law and the emergence of Community law, which in today's social reality is the positive law applicable throughout the European Union.

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Looking at the emergence and development of patients' rights from a philosophical perspective, they represent the totality of human knowledge, beliefs, principles and activities to achieve the ideals of Good and Fairness.

Considering that mankind has entered the era of irreversible development, which depends on the exacerbation of global problems, in order to ensure the co-evolution of man and the environment, and to form a global consciousness, it is necessary to reconceptualise all social relations: man's relations with nature, relations between different communities, relations between man and man, attitudes towards the past, history, culture, state, etc.

2. Theory

In the beginning, the concept of public health was ostensibly paternalistic, even authoritarian. Basic healthcare, as well as pensions, education and other rudimentary welfare, came to be distributed under the auspices of guilds or governments, when the relationship between these services and the rights of the individual was also clear.

The patient had numerous obligations, but no rights in the modern sense. Epidemic control was the reason behind public healthcare and far more important to the authorities than individual well-being.

The discoveries of political democracy, together with economic and scientific progress since then, have changed the power game.

The advancement of citizens' rights in the decades following the First World War became the foundation for the rights of the modern patient. The introduction of the popular vote and the clear definition of citizens' rights created the foundation for articulating a desire for various social services, including healthcare. Scientific progress between the two world wars highlighted the potential to treat an increasing number of diseases, an increasing number of patients and also their rising expectations.

Modern citizenship was the idea, but it should not be limited to voting rights and to participation in formal political decision-making, but should also provide rights in other social spheres, such as the right to work, life, education, housing and healthcare.

The first step towards a more individualistic view of patients came with the HIV movement. In 1985, the Denver Declaration [1] proclaimed that "We condemn the attempt to label us as *victims*, a term which implies defeat, we are only occasionally *patients*, a term which implies passivity, helplessness and dependence upon the care of others. We are *people with AIDS*." Thus, the Denver Declaration is considered one of the main texts concerning the rights of a specific group of patients, in this case people infected with HIV.

During the 1990s, the rapid development of patients' rights took place legally, starting with the WHO European Consultation on the Rights of Patients, held in Amsterdam from 28 to 30 March 1994.

The Council of Europe adopted in 1997 the Oviedo Convention [2] for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Biomedicine, which provides the patient with a catalogue of rights and proclaims his or her fundamental rights.

As a result of these signals, there has been an increase in national regulation of patient rights in almost every European country, even though in some countries patient rights benefited from formal laws, applied according to political culture, such as the right of an individual to take legal action if denied a right to certain services or cases of discrimination based on ethnicity or sexual behaviour.

In some systems, patients' rights are brought together in a general framework, in others there are numerous specialised legislative acts.

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3. Results and discussion

The patient's right to be treated is undoubtedly a major achievement, but it needs to be considered in relation to the content of care and the patient's position when receiving care. Today, for access to healthcare to be comprehensive and individual rights to be respected, the patient must be able to navigate the healthcare system to access the best care.

According to the most recent Health Consumer Report [3], there are still a number of social rights that most governments need to focus on through public policy with respect to individual patient rights.

Frequent public health campaigns about restrictions on smoking, obesity, a healthy diet, or safe active ageing may be perfectly legitimate and serve a good purpose, but in practice mean very little to a patient anxious to access timely cancer treatment, or to be able to access a second medical opinion. The proclamation of patient empowerment means nothing if the patient does not have the right to access and use information, to make choices and to be able to rely on the high quality of the procedures.

Other types of instruments are code-based, such as, for example, the Code of Good Practice on the Rights and Quality of Life of People with Multiple Sclerosis [4] which sets standards for access to quality treatment and procedures for people with multiple sclerosis. Thus, in December 2003, the European Parliament adopted a report based on a petition submitted by a British citizen with multiple sclerosis, Louise McVay. This report was actively supported by the European Multiple Sclerosis Platform (EMSP) and by all national multiple sclerosis societies in the European Union. Health ministries in most EU Member States provided information that was used in the drafting of this report. The EMSP Code was conceived as a natural follow-up to a Resolution of the European Parliament [5] which identified the root causes underlying the discrimination and unequal rights of EU citizens affected by MS and formulated several policy and programmatic initiatives aimed at redressing this situation.

The EU Charter of Fundamental Rights [6] affirms a set of inalienable universal rights that EU bodies and Member States cannot limit and individuals cannot waive.

Article 35 of the Charter of Fundamental Rights provides for a right to health protection, the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. Article 35 specifies that the Union must ensure "a high level of human health protection", in the sense of health as both an individual and a social asset. This wording sets a standard guideline for national governments: they must not stop at the minimum level of guaranteeing standards, but aim for the highest level, despite differences in quality in the various service-providing systems.

In addition to Article 35, the Charter of Fundamental Rights contains many other provisions which refer directly or indirectly to patients' rights and are very valuable in the field of public health. In this regard, we can mention: the inviolability of human dignity, as well as the right to life; the right to the integrity of the person; the right to security; the right to the protection of personal data; the right to non-discrimination, the right to cultural, religious and linguistic diversity; the rights of the child; the rights of the elderly.

In the field of pharmaceuticals, patients' rights have their source in the Community code relating to medicinal products [7], which regulates patients' unrestricted access to safe, effective and quality medicines.

Thus, the World Health Organization defined pharmacovigilance as *" the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem"* [8].

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The early establishment and development of pharmacovigilance under the auspices of the World Health Organisation was based on events and ideas that raised awareness in the human community on the importance of continuous monitoring of the safety of medicines.

Prescribing medicines without respecting the indications, or for indications other than those for which the medicine has been approved, is still common practice in many countries, including the United States. However, this practice can lead to a more widespread occurrence of unanticipated adverse reactions, and often to serious adverse reactions. Healthcare professionals, drug manufacturers and marketing authorisation holders are jointly responsible for and involved in pharmacovigilance activities.

In the last decade, there has been a growing awareness that the scope of pharmacovigilance should be extended beyond the strict limits of detecting new safety problems. Globalisation, consumerism, the explosion of free trade and cross-border communication, and the increase in the use of the internet have led to a change in the way all medicinal products and related information are accessed.

These changes have given rise to new types of safety issues, such as: the illegal sale of medicines and the abuse of medicines on the internet [9]; the rise of self-medication practices; irrational and potentially unsafe practices in the supply of medicines; the increasing use of traditional medicines outside the traditional sphere of use; the increasing use of traditional medicines and herbal medicines together with other medicines with potentially adverse interactions [10].

The large-scale manufacture and sale of counterfeit and substandard medicines is also a major safety concern [11], a phenomenon that is currently being experienced internationally.

It should be emphasised that the increased public expectation of the safety of medicines has added another dimension to pharmacovigilance activities, and this expectation is also a pressure for change.

The falsification of medicines is a global problem and increased and effective international coordination and cooperation is needed to ensure the effectiveness of anti-falsification strategies, particularly in relation to the sale of such products on the internet.

The right of patients to be protected against falsified medicinal products is guaranteed by the provisions of Directive 2011/62/EU [12], which establishes the legal basis for making the falsification of medicinal products a criminal offence, depriving patients of safe and high-quality medical treatment.

In order to ensure patients' access to medicines, Member States ensure that prescriptions issued in another Member State to a particular patient for such a product can be used on their territory in accordance with their own national legislation in force and that any restrictions on the recognition of individual prescriptions are prohibited [13].

However, restrictions may be imposed on the recognition of prescriptions issued in another Member State which are limited to what is necessary and proportionate to safeguard human health and are non-discriminatory.

Restrictions on the recognition of medical prescriptions issued in another Member State may also be imposed where they are based on legitimate and justified doubts as to the authenticity, content or clarity of an individual prescription.

4. Conclusions

Scientific progress in recent decades has highlighted not only the potential to treat an increasing number of diseases, but also the growing number of patients whose expectations have increased.

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Starting from the idea of modern citizenship, which has been extended from electoral rights and participation in formal political decision-making to rights in other social spheres such as the right to work, life, education, housing and healthcare, political will, based on the pragmatic interest of states to have a healthy population, has led to increased national regulation of patients' rights in almost every European country.

We believe it is important to highlight the profoundly social nature of patients' rights. In essence, the right to become a patient, namely to benefit from publicly organised healthcare, was among the first to be recognised. This right was, in fact, a major political issue in the first half of the 20th century, before the acceptance of general health care.

Compared to the social rights granted to citizens collectively, the rights of individual patients must be expressed in absolute terms if they are to be effective. In reality, individual rights - such as the right to timely treatment or to access one's own medical file - are often not expressed precisely enough to have legal force.

Public health policy campaigns have long been dominated by the expression of political will. To meet the challenges of 21st century healthcare, there needs to be a differentiated awareness for each individual patient and the need to strengthen individual rights. Policy must, in this respect, move from the general to the specific.

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